

## AMENDMENTS

Amendments to the Claims

Please amend the claims according to the following listing of the claims.

Listing of the claims

1. (currently amended) An oral dosage form with delayed release of active ingredient and high mechanical stability, comprising:
  - a) one or more active ingredients;
  - b) from 20 to 80%, based on the total weight of the dosage form, of a pre-formulated mixture of polyvinyl acetate and polyvinylpyrrolidone;
  - c) water soluble polymers or lipophilic additives; and
  - d) and other conventional excipients,wherein the ratio of polyvinyl acetate to polyvinylpyrrolidone is from 6:4 to 9:1 and said formulated mixture of polyvinyl acetate and polyvinylpyrrolidone facilitates said delayed release, and wherein said delayed release is defined as limiting the amount of active ingredient released in the first hour to 25.3%, measured according to USP XXIV paddle method, ~~based on the weight of the oral dosage form.~~
2. (canceled)
3. (previously presented) An oral dosage form as claimed in claim 1, wherein a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone in the ratio 8:2 is employed.
4. (previously presented) An oral dosage form as claimed in claim 1, which is a tablet, extrudate, pellet or granulate.

5. (Previously Presented) An oral dosage form as claimed in claim 1, wherein a water-soluble or water-insoluble release-delaying coating is applied to the oral dosage form.
6. (Previously Presented) An oral dosage form as claimed in claim 1, wherein the water-soluble or lipophilic polymers are selected from the group consisting of: polyvinyl alcohols, polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, polyvinylpyrrolidones and derivatives, and vinyl acetate/vinylpyrrolidone copolymers.
7. (Previously Presented) An oral dosage form as claimed in claim 1, wherein the water-soluble swelling polymers are selected from the group consisting of: alginates, pectins, galactomannans, carrageenans, dextran, curdlan, pullulan, gellan, chitin, gelatin, xanthans, hemicelluloses, cellulose derivatives and starch and salts thereof.
8. (Previously Presented) An oral dosage form as claimed in claim 1, wherein the lipophilic additives are selected from the group consisting of: cellulose derivatives, acrylic ester/methacrylic ester copolymers, fatty alcohols, fatty acids, fatty acid esters and fatty alcohol esters, glycerides, waxes, and lecithin.
9. (Previously Presented) An oral dosage form as claimed in claim 1, which is produced by direct compression, extrusion, melt extrusion, pelleting, compaction, wet granulation.
10. (Previously Presented) An oral dosage form as claimed in claim 1, wherein the conventional excipient comprises:  
binder, extenders/fillers, disintegrants, lubricants, flow regulators, dyes, or stabilizers.

11. (Previously Presented) An oral dosage as claimed in claim 1, wherein the formulated mixture of polyvinyl acetate and polyvinylpyrrolidone is present in a proportion of from greater than 20% to less than or equal to 80% based on the total weight of the dosage form.
12. (Previously Presented) An oral dosage form as claimed in claim 1, wherein the water-soluble polymers and/or the lipophilic additives are present in a proportion of from 1 to 40% based on the total weight of the dosage form.
13. (Previously Presented) An oral dosage form as claimed in claim 1, wherein hydroxypropylmethylcellulose are employed as water-soluble polymers.
14. (Previously Presented) An oral dosage form as claimed in claim 1, wherein in polyvinylpyrrolidones or vinyl acetate/vinylpyrrolidone copolymers are employed was water-soluble polymers.
15. (Canceled)
16. (Previously Presented) An oral dosage form as claimed in claim 1, which comprises as active ingredients food supplements or additives, vitamins, minerals or trace elements or active pharmaceutical ingredients.
17. (Previously Presented) An oral dosage as claimed in claim 1, which comprised active pharmaceutical ingredients as active ingredients.
18. (Previously Presented) The dosage form as claimed in claim 1, wherein the active pharmaceutical ingredient is selected from the group consisting of benzodiazepines, antihypertensives, vitamins, cytostatics, anesthetics, neuroleptics, antidepressants, antibiotics, antimycotics, fungicides, chemotherapeutics, urologicals, platelet aggregation inhibitors, sulfonamides, spasmolytics, hormones, immunoglobulins, sera, thyroid therapeutics,

psychopharmaceuticals, antiparkinson agents and other antihyperkinetics, ophthalmologicals, neuropathy products, calcium metabolism regulators, muscle relaxants, lipid-lowering agents, liver therapeutics, coronary agents, cardiac agents, immunotherapeutics, regulatory peptides and their inhibitors, hypnotics, sedatives, gynecologicals, antigout agents, fibrinolytics, enzyme products and transport proteins, enzyme inhibitors, emetics, perfusion promoters, diuretics, diagnostics, corticoids, cholinergics, biliary therapeutics, antiasthmatics, bronchospasmolytics, beta-receptor blockers, calcium channel blockers, ACE inhibitors, arteriosclerosis remedies, antiinflammatory agents, anticoagulants, antihypotensives, antihypoglycemics, antifibrinolytics, antiepileptics, antiemetics, antidotes, antidiabetics, antiarrhythmics, antianemics, antiallergics, anthelmintics, analgesics, analeptics, aldosterone antagonists, and weight-reducing agents.

19. (Canceled)
20. (Canceled)
21. (Canceled)
22. (Previously Presented) An oral dosage form as claimed in claim 6 wherein the water-soluble or lipophilic polymers are selected from the group consisting of polyethylene glycols, polyvinylpyrrolidones, vinyl acetate/vinylpyrrolidone copolymers or maltodextrins, and salts thereof.
23. (Previously Presented) The oral dosage form as claimed in claim 7, wherein the cellulose derivatives are selected from the group consisting of methylcellulose, methylhydroxyethylcellulose, carboxymethylcellulose and wherein the starch derivatives are selected from the group consisting of carboxymethyl starch, degraded starch, polyacrylic acid, polymethacrylic acid, acrylic acid/methacrylic acid copolymers.

24. (Previously Presented) The oral dosage form as claimed in claim 8, wherein the lipophilic additives are selected from the group consisting of cellulose derivatives which are ethylcellulose, cellulose acetate, cellulose acetate phthalate, cellulose acetate succinate, hydroxy propylmethylcellulose acetate phthalate, or hydroxypropylmethylcellulose acetate succinate, acrylic ester/ethacrylic ester copolymers which are methyl methacrylate/ethyl acrylate copolymers, ammoniomethacrylate copolymer type A and type B, methacrylic acid/acrylic ester copolymers or methacrylic acid/ethyl acrylate copolymers, fatty alcohols which are stearyl alcohols, fatty acids which are stearic acid, fatty acid esters and fatty alcohol esters, glycerides, waxes and lecithin.
25. (Withdrawn) A method for making an oral dosage form with delayed release of active ingredient and high mechanical stability by processing an oral dosage form with delayed release of active ingredient and high mechanical stability, comprising combining
- a) one or more active ingredients
  - b) from 20 to 80%, based on the total weight of the dosage form, of a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone
  - c) water soluble polymers or low or high molecular weight lipophilic additives
  - d) and other conventional excipients,
- wherein the ratio of polyvinyl acetate to polyvinylpyrrolidone is from 6:4 to 9:1 and said formulation facilitates said delayed release.
26. (Withdrawn) The method for making an oral dosage form with delayed release of active ingredient and high mechanical stability by processing an oral dosage form with delayed release of active ingredient and high mechanical stability of claim 25 further comprising a step selected from the group consisting of melt extrusion, film coating and press coating.
27. (Previously Presented) An oral dosage form as claimed in claim 1, wherein the

stabilizer comprises an antioxidant, a wetting agent, a preservative, a release agent, a flavoring or a sweetener.

28. (previously presented) The oral dosage form as claimed in claim 1, wherein the water soluble polymers or lipophilic additives of "c)" do not include polyvinyl acetate or polyvinylpyrrolidone.
29. (currently amended) An oral dosage form as claimed in claim 1, wherein the water-soluble or lipophilic ~~polymers~~ additives are selected from the group consisting of: polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, and vinyl acetate/vinylpyrrolidone copolymers.
30. (previously presented) An oral dosage form as claimed in claim 1, wherein the lipophilic additives are selected from the group consisting of: fatty alcohols, fatty acid esters and fatty alcohol esters, glycerides, waxes, and lecithin.
31. (previously presented) An oral dosage form as claimed in claim 1, wherein the oral dosage form is produced by extrusion or melt extrusion.
32. (previously presented) An oral dosage form as claimed in claim 1, wherein the oral dosage form has a friability factor of less than 1%.
33. (previously presented) An oral dosage form as claimed in claim 1, wherein the oral dosage form has a hardness of greater than 200 N.
34. (canceled)